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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,801	05/28/2004	Caroline Desponts	USF-212XZIT	2999
23557	7590	01/11/2007	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			ZARA, JANE J	
			ART UNIT	PAPER NUMBER
			1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)
	10/709,801	DESPONTS ET AL.
	Examiner	Art Unit
	Jane Zara	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 May 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Claims 1-17 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a method of increasing the yield of stem cells in a patient in vivo for autologous transplantation, classifiable in class 514, subclass 44.
- II. Claims 4-6, drawn to a method of increasing the yield of stem cells in a patient ex vivo, classifiable in class 435, subclass 455.
- III. Claims 7-9, drawn to a method of harvesting stem cells from blood, classifiable in class 530, subclass 412.
- IV. Claims 10-17, drawn to a method of promoting recovery of a stem cell population in a patient, classifiable in class 435, subclass 375.

- Applicants are required to elect a single inhibitor pertaining to the elected Group (see e.g., claims 2 and 5).
- Applicants are required to elect a single cell type pertaining to the elected Group (see e.g., claims 3, 6, 8, 13 and 14).

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inhibitors listed are patentably distinct for the following reasons. The different inhibitors listed in claims 2 and 5 are functionally, structurally, biologically and chemically different and distinct. For these reasons, the inventions of the different inhibitors listed in the various Groups are patentably distinct.

Furthermore, searching all of the different inhibitors and methods together would impose a serious search burden. In the instant case, the search of the aptamers and ribozymes, for instance, are not coextensive. There is a search burden also in the non-patent literature to search all of the different inhibitors listed in the different Groups. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of all of the inhibitor Groups together.

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of increasing the yield of stem cells in vivo, ex vivo, of harvesting stem cells from the blood, and promoting recovery of stem cell populations in a patient are all unrelated as they comprise distinct steps and comprise different biological outcomes, which demonstrates that each method has a different mode of operation. The methodology and materials necessary for each of these distinct methods differ significantly: Administration of each of the different inhibitors claimed is

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distinct from each other, and administration of each inhibitor *in vivo* is different and distinct from administration of each of the different inhibitors *in vitro*. In addition, each stem cell type constitutes a biologically, chemically and functionally distinct and different step (e.g. harvesting hematopoietic stem cells, mammary stem cells, mesenchymal and organ specific stem cells each require different and distinct biological steps) and therefore each involves a patentably distinct invention. And the different inhibitors have different and distinct modes of action and constitute chemically, biologically and functionally different and distinct molecules or chemical entities. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups I-IV are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches, each requiring a separate search for the steps and molecules involved in the various methods steps. The searches required for each of the methods would not be coextensive with each other. For these reasons, it would be burdensome to search the inventions of Groups I-IV together, and including each of the different inhibitors and each of the stem cells claimed.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
1-2-07

JZ
TC 16.00

JANE ZARA, PH.D.
PRIMARY EXAMINER